IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Chr. Hansen A/S	Examiner:	Davis, Ruth A
Serial #:	09/813,292	Group art unit:	1651
Filed:	21 March 2001	Docket:	030307-197
Title:	Method for supply of starter cultures having a consistent quality		

DECLARATION BY BØRGE KRINGELUM

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Børge Kringelum having my residence at Vårbuen 48, DK-2750 Ballerup, Denmark, does state and declare as follows:

1. I am an employee at Chr. Hansen A/S, the assignee of the above patent application, and I hold a position as a dairy engineer. Furthermore, I am one of the inventors of the present invention.

2. I am a person skilled in the art to which the above application pertains.

3. I have read and understood the pending claims in that application as well as the office action related thereto dated November 5, 2003, and have the following comments:

4. I have collected data from our propagation factories in the United States to demonstrate that the claimed method according to the invention provides an unexpected advantage over the conventional method of making commercial starter cultures and thus involve a great economic benefit.

5. The conventional method of producing batches of commercial starter cultures begins for each batch at each different propagation factory with a stepwise propagation, i.e. in general two propagation steps, of cells contained in a mother culture of the cell, in order to be able to produce the necessary amount of inoculum material for the inoculation of the final inoculum medium to obtain the desired commercial starter culture.

According to the method of the present invention, batches of commercial starter cultures were produced by using subsets of a stock inoculum material for a direct one-step inoculation of the final inoculum medium to obtain the desired commercial starter cultures. All used subsets originate from the same stock inoculum material produced at our central propagation factory in Denmark.

6. A number of 457 batches of commercial starter culture produced by the conventional method were compared with 115 batches produced by the method of the invention with regard to percentage approved batches.

A batch is said to be approved if the number of cells and the metabolic activity fulfil specified requirements for approval. Furthermore, the test results for bacterial contamination must be passed, in order to get the final approval. If a batch of starter culture is not approved, the batch is to be discarded.

The following starter cultures were used in the above comparison example:

- *B. bifidum* strain

- Mixed cultures R-603 and R-604 comprising *L. lactis* subsp. *lactis* and *L. lactis* subsp. *cremoris*
- *L. acidophilus* strains LA1 and LAK
- *L. pentosus* strain LP-1
- *Pediococcus cereviseae* strain PC3

7. The achieved results are summarised in Table 1. It appears that product approval is increased by 5.25% as a consequence of producing the batches according to the claimed invention, i.e. batches are produced from subsets from the same stock inoculum material and inoculated into the final inoculum medium by a one-step inoculation procedure.

Under the probable assumption that the increased approval rate of 5.25% resulting from a production period lasting two years is representative for our production factories world-wide, a total global cost saving of 1.5 million US$ per year is predictable.

Thus, using the new method the direct production cost is reduced substantially compared to that of the conventional method, mainly because the stepwise propagation of the cells is omitted at the individual propagation factories, which implies that we can be certified that the inoculum (i.e. subset) used for the inoculation of the final inoculum medium has is uncontaminated and has a desired consistent quality, enabling production of commercial starter culture with a higher approval rate. Thus, fewer batches have to be discarded. The implementation of the new method in our propagation factories implies also a great advantage in managing the planning of the production work as the new method generates a high degree of flexibility.

Table 1. Percentage approved batches of commercial starter culture produced by the conventional method and batches produced by the method according to the invention

Starter culture	**No. of batches produced by conventional method**	**No. of batches produced by method of the invention**	**% approved batches produced by conventional method**	**% approved batches produced by method of the invention**
B. bifidum	8	5	38	100
R-603	80	7	79	67
R-604	127	15	84	88
LA1	73	48	84	89
LAK	93	23	78	82
LP1	32	6	91	100
PC3	44	11	87	100
Total	457	115	-	-

8. I hereby declare that all statements made herein, which are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United State Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 02 - 17 - 2004 Name: Børge Kringelum
month/day/year